

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/03/2011

FORM APPROVED

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150097		(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		(X3) DATE SURVEY COMPLETED 08/24/2011	
NAME OF PROVIDER OR SUPPLIER  MAJOR HOSPITAL				STREET ADDRESS, CITY, STATE, ZIP CODE 150 W WASHINGTON ST SHELBYVILLE, IN46176			
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S0000	<p>This visit was for a standard licensure survey.</p> <p>Facility Number: 005086</p> <p>Survey Date: 08/22-24/11</p> <p>Surveyors: Jack I. Cohen, MHA Medical Surveyor</p> <p>John Lee, RN Public Health Nurse Surveyor</p> <p>Janelli Salomon-Angeles Medical Surveyor</p> <p>QA: cloughlin 09/09/11</p>			S0000			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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S0420	410 IAC 15-1.4-2.2 (a)(1)  Reportable events  Sec. 2.2. (a) The hospital's quality assessment and improvement program under section 2 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the hospital: (A) The following surgical events: (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both. (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both. (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention. (BB) Objects present before surgery that were intentionally retained. (CC) Objects not present prior to surgery that						

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	<p>are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:</p> <p>(AA) Catheters.</p> <p>(BB) Drains and other specialized tubes.</p> <p>(CC) Infusion pumps.</p> <p>(DD) Ventilators.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <p>(i) Infant discharged to the wrong person.</p> <p>(ii) Patient death or serious disability associated with patient elopement.</p> <p>(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the hospital, defined as events</p>						

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	<p>that result from patient actions after admission to the hospital. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.</p> <p>(D) The following care management events:</p> <p>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:</p> <p>(AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration.</p> <p>Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the hospital. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:</p> <p>(AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or Stage 4 pressure ulcers</p>						

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	<p>acquired after admission to the hospital. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the hospital.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <p>(i) Patient death or serious disability associated with an electric shock while being cared for in the hospital.</p> <p>Excludes events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <p>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:</p> <p>(AA) contains the wrong gas; or (BB) is contaminated by toxic substances.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the hospital.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the hospital.</p> <p>(F) The following criminal events:</p> <p>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</p> <p>(ii) Abduction of a patient of any age.</p> <p>(iii) Sexual assault on a patient within or on the grounds of the hospital.</p> <p>(iv) Death or significant injury of a patient or</p>						

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S0554	<p>staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the hospital.</p> <p>Based on document review and interview, the hospital failed to include reportable events as part of its quality assessment and performance improvement (QAPI) program.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the facility's QAPI program indicated it did not include reportable events.</li> <li>2. On 8-24-11 at 3:00 pm, employee #A9 was requested to provide the above documentation and none was provided prior to exit.</li> <li>3. On that same date and time, upon interview, the employee indicated there were no reports of reportable events as part of the facility's QAPI.</li> </ol>			S0420	<p>Major Hospital had SPP-AS 42 Adverse Event Reporting Policy in place which includes Indiana reportable events. These reportable events had been reported by exception quarterly (if an event occurred) to Hospital Quality Council (HQC) and annually to HQC when report was submitted to the State. The policy has been updated to include reporting to HQC quarterly and the Indiana reportable events are a standing agenda item for HQC quarterly meetings. These reportable events were discussed at the September 20, 2011 Hospital Quality Council.</p> <p>Person Responsible: Director Medical Staff Support</p>		09/20/2011
	<p>410 IAC 15-1.5-2(a)</p> <p>(a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on observation, the hospital created 1 condition which failed to provide a healthful environment that minimized</p>			S0554	<p>The decision was made that this area should be for Biohazard Waste only. All clean supplies have been removed from this</p>		09/28/2011

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S0570	<p>infection exposure and risk to patients, employees and visitors.</p> <p>Findings:</p> <p>1. On 8-22-11 at 12:20 pm in the presence of employees #A1 and #A2, it was observed in a basement biohazard waste storage area that there was both biohazardous waste and clean supplies (gloves, mopheads, etc.) stored in the same small room. The clean supplies were thus subject to cross contamination.</p> <p>410 IAC 15-1.5-2 (f)(1)(A)(b)(C)(D)(E) (f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (1) The infection control committee shall be a hospital or medical staff committee that meets at least quarterly, with membership that includes, but is not limited to, the following: (A) The person directly responsible for management of the infection surveillance, prevention and control program. (B) A representative from the medical staff. (C) A representative from nursing service. (D) A representative from administration. (E) Consultants from other appropriate services within the hospital, as needed.</p>				<p>room as of September 28, 2011. Monitoring for biohazard waste and clean supplies stored in the same area will be done during monthly Safety Rounds, reported to Safety Committee and reported to Hospital Quality Council quarterly. Person Responsible: Housekeeping Manager and Safety Officer</p>		

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	<p>Based on document review and interview, the facility failed to ensure the Infection Control Committee meets quarterly and has membership that includes the person directly responsible for management of the infection surveillance, prevention and control program, a representative from the medical staff, a representative from nursing service and a representative from administration.</p> <p>Findings include:</p> <p>1. Review of the Medical Staff Bylaws indicated the following: "Infection Control Committee A. The Infection Control Committee shall consist of at least three (3) members of the Active Medical Staff, including the Pathology Service Director. A representative of the Nursing Administration shall be an ex-officio member with vote. A Laboratory Representative and the Infection Preventionist shall be ex-officio members without a vote."</p> <p>These Medical Staff Bylaws were last reviewed/revised on 07-27-11.</p> <p>2. Review of the Infection Control Committee meeting minutes indicated the following: the 11-23-10 meeting lacked</p>			S0570	<p>Medical Staff Bylaws: Article XIII, Section 4 Infection Control Committee A. The Infection Control Committee shall consist of at least three (3) members of the Active Medical Staff, including the Pathology Service Director. A representative of the Nursing Administration shall be an ex-officio member with vote. Recommended revision to state: Representatives of Administration, Nursing or their designee and the Infection Preventionist will be ex-officio members with a vote. Person Responsible: Director Medical Staff Support This revision will be taken for approval to the Medical Executive Committee on October 18, 2011, the Medical Staff on November 8, 2011 and to the Board of Directors for approval on November 28, 2011. All voting members will receive notification of the Infection Control Committees one week prior to the meetings from the Infection Preventionist requesting that they verify that they will be attending the committee meeting. If voting members are unable to attend, a designee will be requested to attend or the Infection Control Committee will be rescheduled. Attendance of voting members will be reported to Hospital Quality Council quarterly. Person Responsible: Infection Preventionist</p>		11/28/2011



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S0732	<p>documentation of having a representative from Administration and Nursing with voting rights.</p> <p>the 01-22-11 meeting lacked documentation of having a representative from Administration and Nursing with voting rights.</p> <p>the 05-24-11 meeting indicated that only 2 physicians attended.</p> <p>3. On 08-23-11 at 1410 hours, staff #50 confirmed that the Infection Preventionist did not have a vote on the Infection Control Committee.</p> <p>410 IAC 15-1.5-4(d)(1)(2)(3)(4)</p> <p>(d) The medical record shall contain sufficient information to:</p> <p>(1) identify the patient;</p> <p>(2) support the diagnosis;</p> <p>(3) justify the treatment; and</p> <p>(4) document accurately the course of treatment and results.</p> <p>Based on document review, the facility failed to ensure that the medical record (MR) contains sufficient information to accurately identify the patient for 1 of 5 Emergency Department MRs reviewed (patient #20).</p> <p>Findings include:</p> <p>1. Review of patient #20's MR indicated</p>			S0732	<p>Medical Record (patient #20) dictation was corrected with the correct age by the ED MD on August 29, 2011. Health Information added to the job duties of the Outpatient Coders to review ED MD dictation when coding ED records to ensure that dictation is accurate on September 13, 2011. Inaccurate information and questions will be forwarded to the ED physicians for clarification/correction. The VP</p>		11/08/2011

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S1020	<p>the following on the Emergency Room Physician Documentation; "Age/sex: 50 F</p> <p>Physician Documentation - 2 year old white female with history of COPD, coronary artery disease, cardiac stent."</p> <p>410 IAC 15-1.5-7 (d)(2)(A)</p> <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(A) Separation of drugs designed for external use from drugs intended for internal use.</p> <p>Based on document review and interview, the hospital failed to ensure the monthly inspection of 2 areas where drugs are stored.</p> <p>Findings:</p> <p>1. Review of hospital Reference Policy: 150-0100 entitled MEDICATION ROOM INSPECTION, indicated all medication</p>			S1020	<p>Nursing discussed the importance of accuracy of physician documentation in Medical Care Evaluation Committee on August 25, 2011, Medical Executive on September 20, 2011 and will discuss at General Medical Staff Committee on November 8, 2011. Accuracy of ED dictation will be reported to Medical Care Evaluation Committee and Hospital Quality Council quarterly. Person Responsible: Health Information Manager</p> <p>Pharmacy staff will inspect Benesse Oncology Center and SportWorks/ReNovo Orthopaedic Center on a monthly basis. Documentation will be sent back to the Pharmacy Manager. The two offsite pharmacy checks will be added to the Pharmacy Quarterly Departmental Quality Report which is forwarded to the Director of Quality Improvement on quarterly basis and reviewed at Hospital Quality Council</p>		09/29/2011

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S1118	<p>storage areas will be inspected monthly using the unit check supply list.</p> <p>2. On 8-22-11 at 11:45 am, a pharmacy staff member was requested to provide documentation of monthly medication checks for 2 offsite areas where drugs are stored, the Benesse Oncology Center and SportWorks/reNovo Orthopaedic Center. No documentation was provided prior to exit.</p> <p>410 IAC 15-1.5-8 (b)(2)</p> <p>(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition shall be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation, the hospital created conditions which resulted in a hazard to patients, public or employees in 3 instances.</p> <p>Findings:</p> <p>1. On 8-22-11 at 11:55 pm in the presence of employees #A1 and #A2, it was observed in the Lab construction area, there was 1 fire extinguisher on the</p>			S1118	<p>quarterly. Person Responsible: Pharmacy Manager.</p> <p>1. &amp; 2. The fire extinguisher had been placed on the floor during painting of department. The fire extinguisher was removed from the floor at the time of the survey. The fire extinguisher cabinet was installed on August 23, 2011. 3. The hand sanitizer was moved on August 23, 2011 to 12 inches away from an electrical outlet. 4. The hand sanitizer was moved on August 23, 2011 to 12 inches away from an electrical outlet. 5. Engineering SOP - Hand</p>		09/26/2011

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	<p>floor unsecured by chain or holder.</p> <p>2. If the above extinguisher was knocked over and broke the head off the compressed cylinder, it could result in harm to people and/or property.</p> <p>3. On 8-22-11 at 2:55 pm in the presence of employees #A1 and #A2, it was observed in a Radiology reading room, there was an alcohol-based hand sanitizer (ABHS) on the wall approximately 2" above and adjacent to an electrical outlet. It was also observed there was streaking on the wall which appeared to be residue from the dispenser.</p> <p>4. On 8-23-11 at 10:20 am in the presence of employees #A1 and #A2, it was observed in the Physical Therapy Gym area of the SportWorks/reNovo Orthopedic Enter offsite, there was an ABHS on the wall directly above an electrical outlet.</p> <p>5. In both of the above cases of the ABHS's, their close location relative to an ignition source posed a fire hazard if the flammable alcohol was sprayed or dropped into the electrical ignition source.</p>				<p>Sanitizers was created and states - Hand sanitizer will not be mounted within 12 inches of a electrical switch or over any outlets. Effective September 2011. Hand sanitizer locations will be monitored during monthly Safety Rounds and reported quarterly to Hospital Quality Council. Securing of fire extinguishers will be monitored during monthly fire extinguisher checks and reported quarterly to the Hospital Quality Council. Person Responsible: Engineering Manager and Safety Officer</p>		

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S1162	<p>410 IAC 15-1.5-8(d)(2)(A)</p> <p>(d) The equipment requirements are as follows: (2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows:</p> <p>(A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, the facility failed to timely make code blue alarm checks for 3 of 7 months in 2011.</p> <p>Findings:</p> <p>1. Review of a document entitled Code Blue Alarm Checks indicated there were to be monthly code blue alarm checks in all areas, [as employees are to] initial each month once code blue checks have been performed for each department.</p> <p>2. Further review of the above document indicated for the first seven (7) months of 2011, there were no initials i.e. monthly checks in March, June and July for the areas of Cardiopulmonary, Nursing Units, Peds Unit, Post Surgical Care, OB, Surgery Department, Physical Therapy,</p>			S1162	<p>Upon review it was found that there was staff turnover at the time of the missing code blue alarm checks and a specific policy about the code blue alarm checks was not in place. Code Blue Alarm Check policy was written and staff were inserviced on code blue alarm checks. The Registration Manager has placed a reminder on her calendar to check for code blue alarm checks by the 19th of each month. Code Blue Alarm checks will be standing agenda item at Safety Committee and reported quarterly to Hospital Quality Council. Person Responsible: Registration Manager</p>		09/28/2011

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150097		(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		(X3) DATE SURVEY COMPLETED 08/24/2011	
NAME OF PROVIDER OR SUPPLIER  MAJOR HOSPITAL				STREET ADDRESS, CITY, STATE, ZIP CODE 150 W WASHINGTON ST SHELBYVILLE, IN46176			
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S1168	<p>Radiology Department and Emergency Department. No further documentation was provided prior to exit and document.</p> <p>410 IAC 150-1.5-8 (d)(3)</p> <p>(d) The equipment requirements are as follows:</p> <p>(3) Defibrillators shall be discharged at least in accordance with manufacturers recommendations and a discharge log with initialed entries shall be maintained.</p> <p>Based on document review and interview, the hospital failed to properly keep a discharge log for 1 defibrillator, according to the manufacturer's recommendations.</p> <p>Findings:</p> <p>1. Review of the manufacturer's recommendations for the OnSite automated external defibrillator (AED) located at the Sleep Lab offsite indicated the following:</p> <p>Maintenance is limited to periodically checking the following:</p> <p>Check the green Ready light. If the green Ready light is not blinking, see Troubleshooting</p> <p>Tips, below.</p> <p>Replace any used, damaged or expired supplies and accessories</p>			S1168	<p>The Crash Cart Committee met on September 28, 2011 and developed SPP No: AS - 76 Automated External Defibrillator (AED) Monthly Operation Checks. This policy outlines who is responsible to check all AEDs: semi-annual preventative maintenance will be done by the Engineering Department, daily checks for: pads attached, Green Ready Light Blinking, if Chirping sound heard, or "I" button flashing - work order and contact BIOMed Engineering will be done by assigned departments (Sleep Center one of them) daily when the department is open. Daily logs will be sent to the Code Blue Team c/o Emergency Department Manager on a monthly basis. Code Blue Team will report to Critical Care Committee and Hospital Quality Council quarterly. Person</p>		09/28/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/03/2011

FORM APPROVED

OMB NO. 0938-0391

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	Check the outside of the OnSite. If you see cracks or other signs of damage, contact Phillips for technical support.  2. On 8-24-11 at 2:45 pm, staff at the Sleep Lab offsite, upon request and interview, indicated there was no policy and periodic checking of the AED. No documentation was provided prior to exit.				Responsible: Emergency Department Manager.		